Examiner has stated that angina pectoris is a specific condition whereas "a neurodegenerative disease" is not. The Examiner's position appears to be that the Markush group must recite specific diseases or broad categories and that the two may not be mixed. Applicant has reviewed MPEP Section 2173.05(h), which is the section directed to Markush groups, and cannot find any mention of such a requirement. In fact the section states that the "materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class." Further, the section also states that "it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship..." Therefore, the Examiner's requirement that only individual diseases can be presented in the Markush group because the Markush group contains angina pectoris is without merit.

Therefore, it is submitted that the rejection is improper as it is based on a requirement not contained in the MPEP. Additionally, as can be seen throughout the specification and, in particular, on page 1, lines 18-23, angina pectoris and neurodegenerative related diseases are treatable with T-type calcium blockers. Accordingly, all of the listed diseases possess this "one property in common" and that the Examiner's rejection is, therefore, improper in light of the MPEP. Therefore, it is requested that the rejection be withdrawn.

c) The Examiner has also rejected Claim 1 for its recitation of "said animal." Claim 1 has been amended to correct the lack of antecedent basis. Additionally, support for the amendment (and new Claim 25) may be found throughout the specification and particularly on page 4, line 15. It is submitted that this amendment is

sufficient to overcome the rejection for Claim 1 and that it also renders the antecedent basis rejection of Claim 24 (for "the animal") moot. Therefore, it is requested that these rejections be withdrawn as well.

d) The Examiner has rejected Claims 2, 4-7, 9, 10, and 22 as indefinite for failing to further limit Claim 1. Claims 2, 4-7, 9, and 22 have been canceled in this Response. Claim 10, however, has been amended to make it dependent upon Claim 1, thereby further limiting Claim 1 by placing a limitation upon the effective amount of Claim 1. Therefore, it is requested that this rejection be withdrawn as well.

e) The Examiner has rejected Claims 11-17 as confusing because they are directed towards non-elected active ingredients. Claims 11-17 have also been cancelled. Therefore, it is requested that this rejection be withdrawn as well.

f) Finally, the Examiner has rejected Claim 24 as a duplicate of Claim 8. Claim 24 has been cancelled. It is requested that this rejection be withdrawn.

Claims 1-17 and 22-24 have been rejected under 35 U.S.C. 102(b) or 35 U.S.C. 102(e) as anticipated by EP 847,756, the Khwaja reference (U.S. Patent No. 6,113,907), or the Meruelo reference (U.S. Patent No. 5,514,714). As Claims 2, 4-7, 9, 11-17, 22 and 24 have been cancelled, it is requested that the rejection be withdrawn as to these claims.

The Examiner noted that the teachings of the '756 reference are of record. The Examiner has taken the position that the present claims are drawn to a method of treating a health disorder treatable with a T-type calcium channel blocker and that the '756 reference teaches treating Hepatitis C with an ethanol extract of *Hypericum perforatum*.

The Examiner has also concluded that because hepatitis is a health disorder and because the extract is being administered to an animal, the extract will inherently block T-type calcium channels in an animal. Therefore, according to the Examiner, the claims are anticipated.

It is submitted that the Examiner has misunderstood the previous arguments regarding these claims. It is understood that the treatment of Hepatitis C with *Hypericum perforatum* extract is disclosed in the '756 reference. However, the '756 reference does not disclose that the diseases claimed in the present application are treatable with *Hypericum perforatum* extract. Therefore, it is submitted that there is no motivation provided by the cited references (nor has the Examiner provided any reason) to believe that *Hypericum perforatum* extract may be used to treat the diseases presently claimed in the application. Otherwise, no second medical use patents would ever issue.

Accordingly, given the absence of any discussion or teaching of the treatment of the claimed treated diseases with an extract of *Hypericum perforatum* in the '756 reference, it is submitted that the present application cannot be anticipated by or obvious over the '756 reference and it is requested that the rejection be withdrawn.

The Examiner has also taken the position that the present invention is anticipated by the Khwaja reference. The Examiner is of the opinion that this reference teaches that St. John's wort can be administered to a patient with cardiac arrythmia, diabetes, and hypertension (as seen in Cols. 23, 27, and 28 of the Khwaja reference). The Examiner appears to be correct. However, it is submitted that while Khwaja is directed towards *Hypericum* generally, the specification discusses *Hypericin* almost exclusively,

and not an extract of *Hypericum perforatum*, as is claimed in the present application. Therefore, it is submitted that the Khwaja reference does not teach all of the claimed limitations of the present invention because the Khwaja reference does not disclose the use of the claimed extracts of *Hypericum perforatum*. Thus, it is submitted that the Khwaja patent cannot anticipate the present invention (or render it obvious) because the Khwaja reference does not disclose the present invention.

It is also submitted that the Khwaja patent never makes a connection between *Hypericum perforatum* (extract) and the said diseases (cardiac arrhythmia, diabetes, and hypertension). Khwaja, however, shows in Cols. 23, 27, and 28 a description in very general terms the types of biological assays that one could use for any natural product (see Section 5.4) or what kind of diseases one could possibly treat with any natural product standardized using the PharmaPrint™ technology (see Section 5.7). It is submitted, however, that there is no teaching directed towards the present invention, nor is there any suggestion of it either. Therefore, it is requested that the rejection be withdrawn for this reason as well.

The Examiner also stated that the Meruelo reference teaches that hypericin and pseudohypericin can be administered to a patient to treat diabetes (see Cols. 1 and 6 and the claims of the Meruelo reference). The Examiner correctly notes that hypericin and pseudohypericin are extracts of *Hypericum perforatum*. However, it is submitted the Examiner's reliance upon this reference to reject the current claims is improper in light of his previous positions. In previous Office Actions, the Examiner required Applicant to select an active ingredient for prosecution, and the Examiner took the position that extract of *Hypericum perforatum* is a different active ingredient than

hypericin. Therefore, it is improper, based upon the prosecution history of this application, to reject the presently claimed *Hypericum perforatum* extract with a reference that discusses hypericin, as hypericin was declared to be a separate and distinct invention from the presently claimed extract of *Hypericum perforatum*. Therefore, it is requested that the rejection be withdrawn for this reason.

it teaches an extract of hypericum perforatum col. 4

It is also submitted that the Meruelo patent discusses T-cell mediated diseases (immune system disorders). However, the cited reference does not discuss T-type calcium channel blockers. It is noted that both T-cell mediated immune diseases and T-type calcium channels are well-described in the literature and that they are two wholly separate groups. It is submitted that no connection has been made between these two groups. Therefore, it is submitted that in light of the above arguments that the rejection is improper and it is requested that the rejection be withdrawn.

The Examiner has also stated that hypertension is treated by the extract of *Hypericum perforatum* in the '756 reference's "treatment" of Hepatitis C. The Examiner has taken the position that because hypertension is a symptom of Hepatitis C, the fact that Hepatitis C is treated by *Hypericum perforatum* extract results in an alleviation of those symptoms. It is the Examiner's contention that this alleviation is treatment.

It is submitted that the rejection is not well taken. It is submitted that the invention of the '756 reference does not treat hypertension. It treats Hepatitis C. As a result of eliminating Hepatitis C, the symptoms of that disease are alleviated. The compound of the '756 reference is <u>not</u> a <u>direct</u> treatment for hypertension. It is submitted that it does not follow that hypertension is treated by the invention of the '756

reference. The '756 reference does not contain any discussion regarding use of the disclosed compound as a hypertension reliever, only as a treatment for Hepatitis C.

Additionally, it is submitted that the reduction of portal hypertension observed in the '756 reference is due to improved liver function and not the treatment of hypertension. The inventors of the '756 reference never connected the reduced blood pressure directly to the given treatment. This is because a person treated for Hepatitis C would normally see a reduction in blood pressure. Additionally, it is submitted that the present invention is claiming the alleviation of hypertension that is caused by T-type calcium channel dysfunction (and not the other types of hypertension). As the cited reference does not discuss this limitation, it is requested that the rejection be withdrawn for this reason as well.

The Examiner has also taken issue with Dr. Pang's declaration. In particular, the Examiner has noted that Dr. Pang never explicitly stated that Hepatitis C, as a virus, could not be treated by using an agent which is only a T-type calcium channel blocker. Attached to this response is an executed copy of a supplemented Declaration. It is requested that the objection to the Declaration be withdrawn.

The Examiner has also rejected the pending claims under 35 U.S.C. 103(a) as obvious in light of the '756 reference and either Khwaja or Meruelo. The Examiner claims that the motivation to combine these references would have been provided from the motivation to treat the claimed diseases and because they are clearly contemplated by the references.

Applicant relies upon the above discussion of the cited references in response to this rejection. It is submitted that these references (either singly or taken together) do

not disclose all of the limitations of the claimed invention. Additionally, it is submitted that there is no motivation to combine these references, even if all of the limitations of the claimed invention were disclosed therein.

As stated previously, the '756 reference does not discuss the claimed treated diseases at all. Therefore, it is submitted that this reference cannot render the claimed invention obvious. As for the supporting references, it is submitted that Khwaja and Meruelo are directed to Hypericin and not to an extract of *Hypericum perforatum*. As explained above, while it is known that Hypericin is an extract of *Hypericum*, the Examiner's prior insistence that hypericin could not be included with extract of *Hypericum perforatum* renders the combination of the references contradictory and inconsistent with the prosecution history of the application. Therefore, the prior decision of the Examiner that *Hypericum perforatum* extract and Hypericin are sufficiently different to be examined separately and that they could not be claimed together renders the current argument that Hypericin is just another extract of *Hypericum perforatum* inappropriate. Thus, it is submitted that the rejection is not well taken and it is requested that this rejection be withdrawn as well.

In the event this paper is not timely filed, Applicant hereby petitions for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300, referring to client-matter number 108061-09013.

Respectfully submitted,

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Enclosures: Marked Up Copy of Claims
Supplemental Declaration
Petition of Extension of Time (3 Months)

## MARKED UP COPY OF CLAIMS

1. (Thrice Amended) A method of treating a health disorder selected from the group consisting of chronic heart failure, congestive heart failure, ischemic condition, arrhythmia, angina pectoris, hypertension, hypoinsulinemia, hyperinsulinemia, diabetes mellitus, hyperaldosteronemia, epilepsy, a neurodegenerative disease and preterm labor in an animal suffering from said disorder, the method comprising administering an effective amount of an active agent to said animal, wherein said active agent consists of an extract of *Hypericum perforatum* and wherein said extract of *Hypericum perforatum* is the only active agent administered according to the method.

10. (Once Amended) The method of claim [9] 1, wherein said effective amount is about 0.05 mg to 500 mg per kg body weight of said animal.